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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/394,019	09/10/1999	AKIRA KOMORIYA	3273.002US1	3625

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EXAMINER
KAM, CHIH MIN

ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 09/10/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application N . 09/394,019	Applicant(s) KOMORIYA ET AL.	
	Examiner Chih-Min Kam	Art Unit 1653	

-- The MAILING DATE of this c mmunicati n appears on the cover sheet with the correspondenc address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 June 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-26* is/are pending in the application.

4a) Of the above claim(s) *16-26* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *18* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I, claims 1-15 and SEQ ID NO:248 in Paper Nos. 23 and 25 is acknowledged. The traversal is on the ground(s) that the search can be made without serious burden even they are directed to distinct inventions. Regarding the requirement for election of one amino acid sequence, one fluorophore, and one hydrophobic group, applicants indicate Examiner fails to indicate which claim(s) are generic and to specifically identify each of the species, for example, it is not clear whether an election of a sequence from claim 1 for the "P" domain or an election of a sequence from claim 4 is required. This is not found persuasive because the traversal is not on the grounds that the inventions are not independent and distinct, rather, the traversal is on the grounds that there is no serious burden. As such restriction is proper if two or more claimed inventions are either independent **or** distinct. See MPEP 803. Furthermore, coexamination of each of the additional groups and sequences would require search of classes and sequences unnecessary for the examination of the elected claims. For example, if Group II were included, it would require additional search of class 435, subclass 325; if more than one sequence were included, it would require search of additional sequences. Therefore, coexamination of each of these inventions would require a serious additional burden of search. Regarding the requirement for election of one amino acid sequence, as indicated in the previous office action, each amino acid sequence is patentably distinct because each sequence is a different chemical entity and has different chemical and physical property, thus, the election of sequence is not a species election. Furthermore, the sequence of "P" domain is encompassed by the sequence in claim 4, thus, if SEQ ID NO:248 is elected in claim 4, the sequence of SEQ ID

NO:212 in claim 1 will be considered, therefore, as long as one sequence is elected either in claim 1 or 4, the related sequence will also be considered.

Upon reconsideration, the requirement for election of one fluorophore and one hydrophobic group is withdrawn, and all the fluorophores in claim 9 and all the hydrophobic groups in claim 12 will be considered, thus, claims 1-15, and SEQ ID Nos:212 and 248 are examined.

The requirement is still deemed proper and is therefore made FINAL.

Informalities

The disclosure is objected to because of the following informalities:

2. The specification is objected to for not conforming C.F.R.37 1.822 (d)(1) since the amino acids in the peptide sequences of the invention are listed with one letter abbreviation (e.g., sequences in Tables 3 and 4) instead of the required three-letter abbreviation with the first letter as an upper case character. Appropriate correction is required.

3. The specification is objected to because of the use of [...] in the text. For example, "Fm-K[F1]DAIPNluSIPK[F1]GY" in Table 12 at pages 55-56. It appears that the instant brackets would indicate deleted material (See the use of "F_1" instead at page 55, lines 7-15) and is thus, confusing as to whether the structure would include "F1 and F2" or not. See also changes to 37 CFR 1.121 in Amendment rules package (Final Rule published on 8 Sep. 2000 (65 Fed. Reg. 54603), see also O. G. of 19 Sep. 2000 (1238 Off. Gaz. Pat. Office 77)). Appropriate correction is required.

Claim Objections

4. Claims 1 and 4 are objected to for not conforming C.F.R.37 1.822 (d) (1) since the amino acids in the peptide sequences have been listed using one letter abbreviation. Use of three-letter format with the first letter as an upper case character is suggested.

Claim Rejections-Obviousness Type Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 1-15 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 5-13 of U. S. Patent 6,037,137. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1-15 in the instant application disclose a fluorogenic composition for the detection of the activity of a protease having the formula cited in claim 1, where P is a peptide having a sequence such as LEHDGIN, F^1 and F^2 are fluorophores, S^1 and S^2 are spacers, aa^1, aa^{10}, aa^2, aa^3, aa^8, aa^9, aa^5, aa^4, aa^6, aa^7, X and Y are defined in the claim. This is obvious in view of claims 1 and 5-13 in the patent which disclose a fluorogenic composition for the detection of the activity of a protease having the formula cited in claim 1, where P is a peptide comprising a protease binding site for the protease, F^1 and F^2 are fluorophores, S^1 and S^2 are spacers, aa^1, aa^{10}, aa^2, aa^3, aa^8, aa^9, aa^5, aa^4, aa^6, aa^7, X and Y are defined in the claim. Both

sets of claims cite a fluorogenic composition for the detection of the activity of a protease having the formula, wherein P is a peptide comprising a protease binding site for the protease such as LEHDGIN. Thus, claims 1-15 in present application and claims 1 and 5-13 in the patent are obvious variations of a fluorogenic composition for the detection of the activity of a protease, which contains a peptide having a protease binding site such as LEHDGIN.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-15 are indefinite because the claim contains non-elected sequences. Claims 2-15 are included in the rejection because they are dependent on a rejected claim and do not correct the deficiency of the claim from which they depend.

7. Claims 1-15 are indefinite because claim 1 recites "aa^2, aa^3, aa^8 and aa^9 are independently selected from the group consisting of an amino acid or a dipeptide", however, there are no dipeptides per se cited in the Markush group "selected from the group consisting of Asp, Glu, Lys...Thr, and Tyr.". Claim 1 also indicates aa^2, aa^3, aa^8 or aa^9 can be an amino acid, according to the formula, $(aa^2\text{-}aa^3)_k$ will be either a dipeptide or no amino acid residue since k is 0 or 1, however, the sequence KDPJGLEHDGINGJPKGY (SEQ ID NO:248) (or other sequences in Tables 3 and 4) would have D as $(aa^2\text{-}aa^3)$, thus, it appears SEQ ID NO: 248 does not conform the formula in claim 1. In claim 1, the formula uses subscripts in F_1 and F_2, while the

explanation text in the claim uses superscripts in F^1 and F^2, since they are not the same, it is unclear which is the correct one? The term "Fm" or "Fmoc" is used in claim 4, 12 or 13, and if "Fm" and "Fmoc" are referred to the same group, only one term should be used. Claims 2-15 are included in the rejection because they are dependent on a rejected claim and do not correct the deficiency of the claim from which they depend.

8. Claim 6 is indefinite because of the use of the term "between about". The term "between about" renders the claim indefinite, it is unclear whether the F1 and F2 have the excitation wavelength below 315 nm as to "about", or in the range of 315-700 nm as to "between". Deletion of "about" is suggested.

9. Claim 9 is indefinite because of the use of the term "other anion". The term "other anion" renders the claim indefinite, it is unclear what other anions are.

10. Claims 10-14 are indefinite because of the use of the term "wherein said composition bears a hydrophobic group". The term "wherein said composition bears a hydrophobic group" renders the claim indefinite, it is unclear where is the hydrophobic group located. Claims 12-14 are included in the rejection because they are dependent on a rejected claim and do not correct the deficiency of the claim from which they depend.

Conclusion

11. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (703) 308-9437. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, Ph. D. can be reached on (703) 308-2923. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-0294 for regular communications and (703) 308-4227 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Chih-Min Kam, Ph. D. CMK
Patent Examiner

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September 4, 2002

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